



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SETTE *et al.*

Appl. No. 09/350,401

Filed: July 8, 1999

For: **Inducing Cellular
Immune Responses to
Hepatitis B Virus Using
Peptide and Nucleic Acid
Compositions**

Confirmation No. 8008

Art Unit: 1644

Examiner: Schwadron, R.

Atty. Docket: 2060.0060008/EKS/PAJ/M-M

First Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental IDS is a continuation of the numbering in Applicants' Information Disclosure Statement filed electronically herewith in connection with the above-captioned application. Copies of documents AL2, AM2, AO2, AS1, AR5, AR20 and AS21 were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/239,043, filed January 27, 1999, which is relied upon for an earlier filing date under 35 U.S.C. § 120 and submitted as document AT42 as cited on the Second Supplemental IDS filed herewith. Thus, copies of the above-listed documents are not attached. 37 C.F.R. § 1.98(d). Copies of all other documents are attached.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents AM1, AP1, and AN2 cited on Form PTO 1449:

Document **AM1**, European Application No. EP 0 226 513 A1, is in the French language. An unverified English language abstract of document AM1 is attached as document **AS25**.

Document **AP1**, PCT International Publication No. WO 92/21033, is in the German language. An unverified English language abstract of document AP1 is attached as document **AT25**.

Document **AN2**, PCT International Publication No. WO 94/11738, is in the German language. An unverified English language abstract of document AN2 is attached as document **AR26**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits. No fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Peter A. Jackman
Attorney for Applicants
Registration No. 45,986

Date: August 5, 2003

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600



FORM PTO-1449

FIRST SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
2060.0060008/EKS/PAJ/M-MAPPLICATION NO.
09/350,401APPLICANT
SETTE et al.FILING DATE
July 8, 1999GROUP
1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA1						
	AB1						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL1	EP 0 044 710 A1	01/27/1982	Europe			Yes No
	AM1	EP 0 226 513 A1	06/24/1987	Europe			Yes X No
	AN1	WO 92/02543 A1	02/20/1992	WIPO			Yes No
	AO1	WO 92/12996 A2	08/06/1992	WIPO			Yes No
	AP1	WO 92/21033 A1	11/26/1992	WIPO			Yes X No

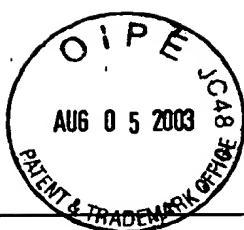
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>1</u>	Aichele, P., et al., "Antiviral cytotoxic T cell response induced by in vivo priming with a free synthetic peptide," <i>J. Exp. Med.</i> 171:1815-1820, Rockefeller University Press (1990)
	AS	<u>1</u>	Alexander, J., et al., "Derivation of HLA-A11/K ^b Transgenic Mice. Functional CTL Repertoire and Recognition of Human A11-Restricted CTL Epitopes," <i>J. Immunol.</i> 159:4753-4761, The American Association of Immunologists (1997)
	AT	<u>1</u>	Bergmann, C.C., et al., "Differential Effects of Flanking Residues on Presentation of Epitopes from Chimeric Peptides," <i>J. Virol.</i> 68:5306-5310, American Society for Microbiology (August 1994)

EXAMINER

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 93/03764 A1	03/04/1993	WIPO			Yes No
	AM2	WO 94/03205 A1	02/17/1994	WIPO			Yes No
	AN2	WO 94/11738 A1	05/26/1994	WIPO			Yes X No
	AO2	WO 94/20127 A1	09/15/1994	WIPO			Yes No
	AP2	WO 96/03140 A1	02/08/1996	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	2	Bertoni, R., et al., "Human Histocompatibility Leukocyte Antigen-binding Supermotifs Predict Broadly Cross-reactive Cytotoxic T Lymphocyte Responses in Patients with Acute Hepatitis," <i>J. Clin. Invest.</i> 100:503-513, The American Society for Clinical Investigation, Inc. (1997)	
AS	2	Bertoni, R., et al., "Human Class I Supertypes and CTL Repertoires Extend to Chimpanzees," <i>J. Immunol.</i> 161:4447-4455, American Association of Immunologists (1998)	
AT	2	Bjorkman, P.J., et al., "Structure of the human class I histocompatibility antigen, HLA-A2," <i>Nature</i> 329:506-512, Macmillan Publishers, Ltd. (1987)	

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AT42. Thus, copies of the above-listed documents are not attached. 37 C.F.R. § 1.98(d).

A copy of all other documents is attached.

The Examiner's attention is directed to the following co-pending U.S. patent applications:

U.S. Application No. 08/591,502, filed May 20, 1996;

U.S. Application No. 09/350,401, filed July 8, 1999;

U.S. Application No. 09/239,043, filed January 27, 1999; and

U.S. Application No. 10/363,990, filed March 10, 2003;

which are directed to related technical subject matter. The identification of these U.S. patent applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

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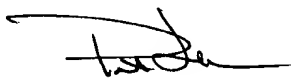
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Peter A. Jackman
Attorney for Applicants
Registration No. 45,986

Date: August 5, 2003

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FORM PTO-1449 <u>SECOND SUPPLEMENTAL</u> <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 2060.0060008/EKS/PAJ/M-M	APPLICATION NO. 09/350,401
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	EP 0 429 816 A1	06/05/1991	Europe			Yes No
	AM3	EP 0 469 281 A1	02/05/1992	Europe			Yes No
	AN3	EP 0 491 077 A1	06/24/1992	Europe			Yes No
	AO3	WO 93/03753	03/04/1993	WIPO			Yes No
	AP3	WO 94/19011	09/01/1994	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR		
	AS	26	Alexander, J., et al., "The Optimization of Helper T Lymphocyte (HTL) Function in Vaccine Development," <i>Immunol. Res.</i> 18:79-92, Humana Press Inc. (1998).
	AT	26	Ando, K., et al., "Mechanisms of Class I Restricted Immunopathology. A Transgenic Mouse Model of Fulminant Hepatitis," <i>J. Exp. Med.</i> 178:1541-1554, The Rockefeller University Press (November 1993).

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	AL4	WO 95/03777	02/09/1995	WIPO			Yes No
	AM4	WO 95/22317	08/24/1995	WIPO			Yes No
	AN4	WO 99/45954	09/16/1999	WIPO			Yes No
	AO4	EP 1 018 558 A2	07/12/2000	Europe			Yes No
	AP4	WO 02/19986 A1	03/14/2002	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>27</u>	Barnaba, V., et al., "Selective killing of hepatitis B envelope antigen-specific B cells by class I-restricted, exogenous antigen-specific T lymphocytes," <i>Nature</i> 345:258-260, Nature Publishing Co. (1990).
	AS	<u>27</u>	Bertoletti, A., et al., "Definition of a Minimal Optimal Cytotoxic T-Cell Epitope within the Hepatitis B Virus Nucleocapsid Protein," <i>J. Virol.</i> 67:2376-2380, American Society for Microbiology (April 1993).
	AT	<u>27</u>	Bertoletti, A., et al., "Natural variants of cytotoxic epitopes are T-cell receptor antagonists for antiviral cytotoxic T cells," <i>Nature</i> 369:407-410, Nature Publishing Co. (June 1994).

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>28</u>	Bertoletti, A., et al., "HLA class I-restricted human cytotoxic T cells recognize endogenously synthesized hepatitis B virus nucleocapsid antigen," <i>Proc. Natl. Acad. Sci. USA</i> 88:10445-10449, National Academy of Sciences (1991).
	AS	<u>28</u>	Bertoni, R., et al., "Human Histocompatibility Leukocyte Antigen-binding Supermotifs Predict Broadly Cross-reactive Cytotoxic T Lymphocyte Responses in Patients with Acute Hepatitis," <i>J. Clin. Invest.</i> 100:503-513, The American Society for Clinical Investigation, Inc. (1997).
	AT	<u>28</u>	Bhatnagar, P.K., et al., "Immune response to synthetic peptide analogues of hepatitis B surface antigen specific for the a determinant," <i>Proc. Natl. Acad. Sci. USA</i> 79:4400-4404, National Academy of Sciences (1982).

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	AR	29	Borras-Cuesta, F., et al., "Engineering of immunogenic peptides by co-linear synthesis of determinants recognized by B and T cells," <i>Eur. J. Immunol.</i> 17:1213-1215, VCH Verlagsgesellschaft mbH (1987).
	AS	29	Bruss, V., "A Short Linear Sequence in the Pre-S Domain of the Large Hepatitis B Virus Envelope Protein Required for Virion Formation," <i>J. Virol.</i> 71:9350-9357, American Society for Microbiology (1997).
	AT	29	Celis, E., et al., "Recognition of Hepatitis B Surface Antigen by Human T Lymphocytes," <i>J. Immunol.</i> 140:1808-1815, The American Association of Immunologists (1988).

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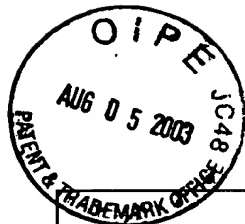
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>30</u>	Chang, K.-M., et al., "Identification of HLA-A3 and -B7-Restricted CTL Response to Hepatitis C Virus in Patients with Acute and Chronic Hepatitis C," <i>J. Immunol.</i> 162:1156-1164, The American Association of Immunologists (1999).
	AS	<u>30</u>	Chisari, F.V., "Hepatitis B Virus Immunopathogenesis," <i>Annu. Rev. Immunol.</i> 13:29-60, Annual Reviews Inc. (1995).
	AT	<u>30</u>	del Guercio, M.-F., et al., "Binding of a Peptide Antigen to Multiple HLA Alleles Allows Definition of an A2-Like Supertype," <i>J. Immunol.</i> 154:685-693, The American Association of Immunologists (1995).

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	AR	<u>31</u>	Diepolder, H.M., et al., "Immunodominant CD4 ⁺ T-Cell Epitope within Nonstructural Protein 3 in Acute Hepatitis C Virus Infection," <i>J. Virol.</i> 71:6011-6019, American Society for Microbiology (1997).
	AS	<u>31</u>	Fayolle, C., et al., "In Vivo Induction of Cytotoxic T Cell Response by a Free Synthetic Peptide Requires CD4 ⁺ T Cell Help," <i>J. Immunol.</i> 147:4069-4073, The American Association of Immunologists (1991).
	AT	<u>31</u>	Ferrari, C., et al., "Identification of Immunodominant T Cell Epitopes of the Hepatitis B Virus Nucleocapsid Antigen," <i>J. Clin. Invest.</i> 88:214-222, The American Society for Clinical Investigation, Inc. (1991).

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	AR	<u>32</u>	Fujii, N., et al., "Synthesis of Peptide Fragments of Hepatitis B Virus Surface Antigen (HbsAg) and Their Immunogenicity," in <i>Peptide Chemistry</i> , Munekata, E., ed., Protein Research Foundation, Osaka, Japan, pp. 215-220 (1983).
	AS	<u>32</u>	Hayashi, Y., et al., "Studies on Peptides. CLXVI. Solid-Phase Syntheses and Immunological Properties of Fragment Peptides Related to Human Hepatitis B Virus Surface Antigen (HbsAg) and Its Pre-S2 Gene," <i>Chem. Pharm. Bull.</i> 36:4993-4999, Pharmaceutical Society of Japan (1988).
	AT	<u>32</u>	Hopp, T.P., "Immunogenicity of a Synthetic HbsAg Peptide: Enhancement by Conjugation to a Fatty Acid Carrier," <i>Mol. Immunol.</i> 21:13-16, Pergamon Press Ltd. (1984).

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AR	<u>33</u>	Ishioka, G.Y., et al., "Class I MHC-restricted, Peptide-specific Cytotoxic T Lymphocytes Generated by Peptide Priming In Vivo," in <i>Vaccines 90</i> , Brown, F., et al., eds., Cold Spring Harbor Laboratory Press, pp. 7-11 (1990).
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	AT	35	Penna, A., et al., "Cytotoxic T Lymphocytes Recognize an HLA-A2-restricted Epitope within the Hepatitis B Virus Nucleocapsid Antigen," <i>J. Exp. Med.</i> 174:1565-1570, The Rockefeller University Press (1991).

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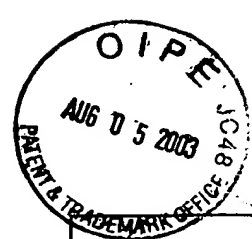
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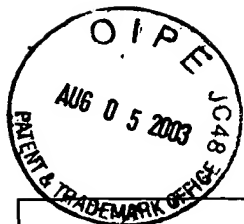
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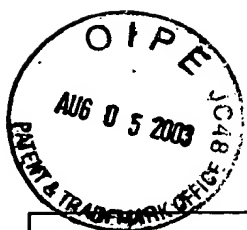
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	AR	<u>2</u>	Geysen, H.M., et al., "Cognitive Features of Continuous Antigenic Determinants," <i>J. Mol. Recognit.</i> 1:32-41, Heyden & Sons, Ltd. (1988)
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	AR	<u>10</u>	Hill, A., et al., "Characterization of two Epstein-Barr virus epitopes restricted by HLA-B7," <i>Eur. J. Immunol.</i> 25:18-24, VCH Verlagsgesellschaft mbH (1995)
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	AR	<u>12</u>	Kast, W.M., <i>et al.</i> , "Protection against lethal Sendai virus infection by <i>in vivo</i> priming of virus-specific cytotoxic T lymphocytes with a free synthetic peptide," <i>Proc. Natl. Acad. Sci. USA</i> 88:2283-2287, National Academy Press (1991)
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	AR	<u>13</u>	Lipford, G.B., et al., "Primary in Vivo Responses to Ovalbumin. Probing the Predictive Value of the K ^b Binding Motif," <i>J. Immunol.</i> 150:1212-1222, The American Association of Immunologists (February 1993)
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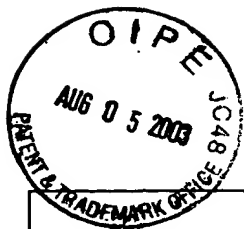
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	AR	<u>15</u>	Pamer, E.G., et al., "Precise prediction of a dominant class I MHC-restricted epitome of <i>Listeria monocytogenes</i> ," <i>Nature</i> 353:852-855, Macmillan Publishers, Ltd. (1991)
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	AT	<u>15</u>	Parker, K.C., et al., "Peptide Binding to HLA-A2 and HLA-B27 Isolated from <i>Escherichia coli</i> ," <i>J. Biol. Chem.</i> 267:5451-5459, American Society for Biochemistry and Molecular Biology, Inc. (March 1992)

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	AR	<u>16</u>	Parker, K.C., et al., "Sequence motifs important for peptide binding to the human MHC class I molecule, HLA-A2," <i>J. Immunol.</i> 149:3580-3587, American Association of Immunologists (December 1992)
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	AT	<u>19</u>	Rudinger, J., "Characteristics of the amino acids as components of a peptide hormone sequence," in <i>Peptide Hormones</i> , Parsons, J.A., ed., University Park Press, Baltimore, MD, pp.1-7 (1976)

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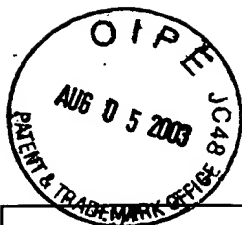
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	AR	<u>21</u>	Sette, A., et al., "Random association between the peptide repertoire of A2.1 class I and several different DR class II molecules," <i>J. Immunol.</i> 147:3893-3900, The American Association of Immunologists (1991)
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

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	AR	22	Sherman, L.A., et al., "Extracellular Processing of Peptide Antigens That Bind Class I Major Histocompatibility Molecules," <i>J. Exp. Med.</i> 175:1221-1226, The Rockefeller University Press (May 1992)
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	AT	22	Sidney, J., et al., "Several HLA Alleles Share Overlapping Peptide Specificities," <i>J. Immunol.</i> 154:247-259, The American Association of Immunologists (1995)

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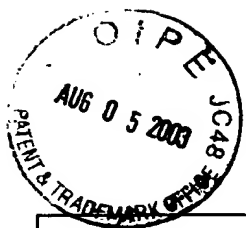
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	AR	24	Yewdell, J.W., and Bennink, J.R., "Cell Biology of Antigen Processing and Presentation to Major Histocompatibility Complex Class I Molecule-Restricted T Lymphocytes," <i>Adv. Immunol.</i> 52:1-123, Academic Press (July 1992)
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	AT	24	Zhang, Q-J., et al., "An HLA-A11-specific motif in nonamer peptides derived from viral and cellular proteins," <i>Proc. Natl. Acad. Sci. USA</i> 90:2217-2221, National Academy Press (March 1993)

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	AR	<u>25</u>	Parker, K.C., et al., "Scheme for Ranking Potential HLA-A2 Binding Peptides Based on Independent Binding of Individual Peptide Side-Chains," <i>J. Immunol.</i> 152:163-175, The American Association of Immunologists (January 1994)
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	AT	<u>25</u>	Dialog File 351, Accession No. 9263567, Derwent WPI English language abstract for WO 92/21033.

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	AR	26	Dialog File 351, Accession No. 9888606, Derwent WPI English language abstract for WO 94/11738.
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